

<b>Case Number:</b>	CM15-0107503		
<b>Date Assigned:</b>	06/12/2015	<b>Date of Injury:</b>	04/27/2012
<b>Decision Date:</b>	07/13/2015	<b>UR Denial Date:</b>	05/14/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/04/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Internal Medicine

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 52 year old female, who sustained an industrial injury on April 27, 2012. Treatment to date has included medications. Currently, the injured worker complains of constant severe pain in the low back with radiation of pain to the bilateral legs. She rates her pain a 9 on a 10-point scale and currently uses Tylenol #3 for pain relief. On physical examination the injured worker has restricted range of motion of the lumbar spine and right radiculopathy. The diagnoses associated with the request include lumbar intervertebral disc without myelopathy. The treatment plan includes Flector patch for pain and follow-up evaluation.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Flector Patch x 30 Units:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113.

NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73. Decision based on Non-MTUS Citation FDA Flector <http://www.drugs.com/pro/flector.html>.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) indicates that nonsteroidal anti-inflammatory drugs (NSAID) can cause gastrointestinal irritation or ulceration or, less commonly, renal or allergic problems. Studies have shown that when NSAIDs are used for more than a few weeks, they can retard or impair bone, muscle, and connective tissue healing and perhaps cause hypertension. Therefore, they should be used only acutely. The primary treating physician's progress report dated 4/20/15 documented a date of injury of 04-27-2012. The patient complained of low back pain radiating to bilateral legs. Patient is alert and oriented. Coordination is grossly intact. Motor and sensory are intact. Speech is intact. Patient has restricted range of motion of lumbar spine. Diagnosis is lumbar intervertebral disc. Flector patch was prescribed. ACOEM indicates that nonsteroidal anti-inflammatory drugs (NSAID) should be used only acutely. The patient's occupational injuries are chronic. Per FDA guidelines, Flector Patch is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions. Medical records document that the occupational injuries are chronic. MTUS and FDA guidelines do not support the request for Flector. Therefore, the request for Flector patch is not medically necessary.